## Exhibit 7

Declaration of Dr. Christina Francis

## IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

## ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS, on behalf of itself, its members, and their patients; AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of itself, its members, and their patients; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS, on behalf of itself, its members, and their patients; SHAUN JESTER, D.O., on behalf of himself and his patients; REGINA FROST-CLARK, M.D., on behalf of herself and her

himself and his patients, Plaintiffs,

patients; TYLER JOHNSON, D.O., on behalf of himself and his patients; and GEORGE DELGADO, M.D., on behalf of

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; JANET WOODCOCK, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration PATRIZIA CAVAZZONI, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; U.S. DEPARTMENT OF **HEALTH AND HUMAN SERVICES**; and XAVIER BECERRA, in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No.	
Case Ito.	

## DECLARATION OF DR. CHRISTINA FRANCIS

- I, Christina Francis, a citizen of the United States of America and a resident of Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.
  - I am over eighteen years old and make this declaration on personal knowledge.
  - 2. I am a board-certified Obstetrician and Gynecologist (OB/Gyn) in good standing and licensed to practice in Indiana. I have been in active practice for 14 years and have worked for the last six years as an OB/Gyn Hospitalist in Fort Wayne, Indiana.
  - 3. As an OB/Gyn Hospitalist, my practice is completely hospital-based. I manage both high- and low-risk pregnancies and deliveries, obstetric critical care, gynecological emergencies presenting to our Emergency Department, and inpatient obstetric and gynecologic consultations.
  - 4. I am a member of the Board of Directors of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG). I am also the CEO-elect of AAPLOG.
  - 5. I am familiar with AAPLOG, its policy positions, its members, the members' interests and concerns. AAPLOG and its members oppose elective abortions, both surgical and chemical.
  - 6. AAPLOG is the largest organization of pro-life obstetricians and gynecologists ("OB/Gyns") in the world and is headquartered in Indiana.

AAPLOG includes OB/Gyns and other physicians, with more than 7,000 medical professionals nationwide and more than 300 members in Texas.

AAPLOG members oppose elective abortion and are committed to the care and well-being of their patients including both pregnant women and their unborn children. AAPLOG members are concerned about the adverse impacts of chemical abortion on their practice of medicine.

- 7. AAPLOG's mission includes advocating on behalf of its members, including in litigation.
- 8. AAPLOG sues in this case on behalf of itself and its members.
- 9. I am familiar with the FDA's regulation of chemical abortion drugs, including mifepristone and misoprostol.
- 10. I have seen first-hand the complications that can result from use of these dangerous chemical abortion drugs. Although Fort Wayne does not have an abortion facility, I have seen several women present with complications after seeking chemical abortions with mifepristone and misoprostol.
- 11. The frequency of these complications has increased since a federal district court first enjoined and set aside the FDA's in-person dispensing requirement for mifepristone in 2020.
- 12. As an example of how chemical abortion harms my patients and my medical practice, one of my patients had obtained mifepristone and misoprostol from a website, without an in-person visit. She was told that the drugs would come from India. After taking the chemical abortion drugs, she began having very

heavy bleeding followed by significant abdominal pain and a fever. When I saw her in the emergency room, she had evidence of retained pregnancy tissue along with endometritis, an infection of the uterine lining. She also had acute kidney injury, with elevated creatinine. She required a dilation and curettage (D&C) surgery to finish evacuating her uterus of the remaining pregnancy tissue and hospitalization for intravenous (IV) antibiotics, IV hydration, and a blood transfusion. I spent several hours with her the day of her surgery/hospital admission, keeping me from my primary patient responsibilities in the labor and delivery unit and requiring me to call in an additional physician to help cover those responsibilities.

13. As an additional example, a partner of mine and I cared for another patient who also suffered complications from chemical abortion. I had taken care of her when she was hospitalized for hyperemesis gravidarum at 9 weeks 5 days gestation. She was discharged home in good condition after significant improvement with medications. During that hospital stay, she had an ultrasound, which showed a healthy pregnancy with no apparent complications and a strong fetal heart rate. During her hospitalization, she expressed to me that she was considering abortion because of experiencing hyperemesis but was unsure. Approximately one week after her discharge, the patient presented back at our emergency room with heavy vaginal bleeding and unstable vital signs as a result of taking chemical abortion drugs. One of my partners was able to detect a fetal heartbeat. Due to the

amount of bleeding that she was experiencing and evidence of hemodynamic instability, however, my partner had no choice but to perform an emergency D&C. The patient needed to be hospitalized overnight for close observation after the D&C. Not only did my partner need to provide several hours of critical care for this patient, but my partner also needed to call in a back-up physician to care for another critically ill patient. And because the preborn baby still had a heartbeat when the patient presented, my partner felt as though she was forced to participate in something that she did not want to be a part of—completing the abortion.

- 14. As we see an increasing number of complications related to chemical abortions, it will place a greater strain on our healthcare system (especially in light of the fact that we are in the midst of a nationwide blood shortage and there are several healthcare deserts where there are no OB/Gyn's), and more physicians with ethical and medical objections to abortion will be forced to participate in completing unfinished elective chemical abortions in emergency situations, just as my partner was.
- 15.AAPLOG members are opposed to being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location. Accordingly, AAPLOG and our members are harmed by the FDA's repeated removal of

- necessary safeguards, which may force them to treat women and girls seeking the completion of an elective chemical abortion.
- 16.AAPLOG, its members, and their patients are also harmed by the FDA's actions that require prescribers to report only deaths and no other complications associated with chemical abortion. As a physician, I know that other complications have significant impacts on my patients as well as our healthcare system. Therefore, the FDA should require reporting of these complications too. But the system for reporting adverse events is not set up to be conducive for busy physicians to report these complications and takes a significant amount of time.
- 17. To report complications to the manufacturer, Danco, a form must be printed, filled out by hand, and then either mailed or scanned and emailed back.

  Much of the information required by this form is impossible to obtain by the physician seeing the patient if they were not the one who dispensed the chemical abortion drugs (such as lot number and dosage)—forcing me to leave several fields blank. I never received confirmation from Danco whether the complications I reported were recorded or reported to the FDA.
- 18. In addition to reporting to the manufacturer, the process of reporting to the FDA Adverse Event Reporting System (FAERS) is also cumbersome. The actual form to be filled out is not easy to find online—requiring several steps to get to it. It once took me two hours to get the website to accept submission of the form, taking me away from the care of my other patients. The

minimum amount of time I have spent reporting a mifepristone complication to the FAERS is thirty minutes—valuable time that should be spent in patient care.

- 19. The FDA's failure to require reporting of all adverse events, combined with its inadequate reporting system, prevents AAPLOG from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.
- 20. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates AAPLOG's purpose to support women's health and to educate doctors, their patients, and the public about these dangers. It forces physicians to actually provide their patients with inaccurate information, leading to the lack of fully informed consent for women.
- 21.AAPLOG needs to divert limited time, energy, and resources to compensate for this lack of information by conducting our own studies and analyses of the available data. This diversion of time, energy, and resources comes to the detriment of other advocacy and educational efforts of AAPLOG, including our efforts regarding the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages.
- 22. In 2002, AAPLOG submitted a Citizen Petition challenging the FDA's approval of Mifeprex and requesting an audit of the Mifeprex clinical studies.

AAPLOG, as an organization, is concerned about women's health issues and recognized that the FDA's violations of its standards and rules in approving Mifeprex put women's lives and health at risk. It took considerable time, energy, and resources to draft the 92-page petition and the 30-page response to comments letter, in addition to compiling and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

- 23. Later, in 2019, AAPLOG submitted another Citizen Petition challenging the FDA's 2016 major changes to the chemical abortion drug regimen. It also took considerable time, energy, and resources to draft the 26-page petition, in addition to compiling and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.
- 24. Because abortion activists continue to file their own citizen petitions and letters with the FDA asking the agency to eliminate all protections for women and girls who take chemical abortion drugs, and knowing the Biden administration's relentless, politicized efforts to push these drugs throughout the country, AAPLOG continues to expend considerable time, energy, and resources on its public advocacy and educational activities regarding chemical abortion drugs—to the detriment of other AAPLOG priorities and functions. This diversion of time, energy, and resources will not cease until the FDA's approval and deregulation of chemical abortion drugs ceases.

Executed this November \_\_\_\_\_\_, 2022.

Christina Francis, M.D.